Image-Guided Cancer Interventions

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The official link for this solicitation is: http://grants.nih.gov/grants/guide/pa-files/PA-10-079.html

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Description:

Purpose

The purpose of this funding opportunity is to support the development and clinical validation of systems for image-guided interventions (IGIs) for cancer. Specifically, the goals of this program are to provide support for:

- The development and optimization of fully integrated cancer imaging, monitoring, and therapy systems;
- Validation of integrated image-guided intervention (IGI) systems through clinical evaluations;
- The development of multiple prototype integrated IGI systems as required for multisite clinical evaluations; and
- Partnerships among small business, large business, and academic clinical centers, as well as small business joint ventures, in order to reach the research goals.

This FOA will use the Small Business Innovation Research (SBIR) program (R43/R44) grant mechanism(s) for Phase I, Phase II, and Fast-Track applications and runs in parallel with an FOA of identical scientific intent, PA-10-080 that encourages applications under the Small Business Technology Transfer (STTR) program (R41/R42) grant mechanisms.

Background

Recent advances in biomedical technologies that combine imaging with energy- and drug-delivery capabilities have stimulated the need for an integrated systems development approach and subsequent clinical evaluation of IGI for cancer. IGIs may be subdivided into three general categories: image-guided-diagnosis (IGD), image-guided-surgery (IGS), and image-guided-therapy (IGT). The common theme of all IGI applications is “image guidance”, linking imaging and interventions. This crucial linkage implies the need for integration at both development and application stages of IGI. Historically, research on IGI technologies has primarily focused on development of components that perform certain tasks in the IGI process, such as stereotactic localization or thermal ablation of tumors. Although researchers have used these systems to establish clinical feasibility, the lack of fully integrated and optimized IGI systems has been a major obstacle in further advancement of clinical IGIs in cancer. Furthermore, the complexity of IGI methods is expected to increase as versatile new biomedical technologies, such as molecular imaging, microelectromechanical systems (MEMS), nanotechnology, and robotics, find their way into the interventional suite in order to improve target identification and treatment efficacy. Hence, there is a growing need to go beyond the clinical feasibility stage for components of image-guided systems and develop, and clinically evaluate, integrated IGI systems for treatment of a variety of cancers. The aim of this program is to stimulate a systems approach for integration and clinical testing of IGI technologies for treatment of cancer.

The importance of developing oncologic IGI techniques has been emphasized in several recent NCI Progress Review Group (PRG) reports. Moreover, the significance of small business contributions to the field of IGI was emphasized in several recent IGI-related NCI workshops. In order to meet the objectives of IGI systems integration, optimization, and subsequent clinical evaluation, partnerships between small businesses that develop the component technologies and major imaging companies that provide the imaging platforms are encouraged. Moreover, partnerships between small businesses and clinical sites may be necessary for the clinical evaluation of IGI products in cancer patients. Because of the complexity of the technologies involved, there may be a need for small companies to develop joint ventures in order to leverage the experience of different companies and to pool their resources for integration of the component technologies.

Scope

Areas of activity that are encouraged for this funding opportunity include, but are not limited to, research, and development in the integration and optimization of some or all of the following component systems into an imaging system as a fully integrated IGI system, and clinical evaluations of the IGI systems for cancer. The component systems include:

(a) Energy (e.g., electromagnetic radiation, heat, cold) delivery and monitoring;

(b) Drug and gene delivery;

(c) Real-time data registration, analysis, and display;

(d) Robotics;

(e) Microelectromechanical systems (MEMS) and microfluidics

(f) Nanodevices and nanoparticles;

(g) Device tracking;

(h) Physiological monitoring;

(i) Intraluminal devices, such as balloons, stents, coils, and endoscopes.

In the context of this funding opportunity, “integration” refers to the integration at the hardware and software levels when appropriate, in order to allow centralized, imaging-based operation and control

of the IGI system.

Examples of integrated IGI systems include: (i) combined imaging and ablation systems, (ii) combined MEMS, device tracking, and imaging systems, (iii) integration of various magnetic resonance pulse sequences for physiological and anatomical mapping for targeting and monitoring in IGI applications, (iv) integrated non-rigid registration, surgical, and imaging system, or (v) nanotechnology-enabled combined imaging and therapy systems. Clinically localized primary or metastatic tumors of the brain, lungs, breast, liver, kidneys, pancreas, prostate, and bone are sites where IGI is likely to find early applications. Some clinical applications of integrated IGI systems include: (i) developing a systems approach for serial acquisition of tissue specimens from solid tumors over time, including implantable devices, (ii) therapeutic delivery of energies, drugs, and genes to tumors, (iii) surgical resection of brain or other tumors guided by real-time physiological and anatomical imaging, and (iv) IG-diagnosis and therapy of small cancerous lesions in various organ systems. It is recognized that the complexity of the IG system proposed and the required level of support will depend on the scope of the proposed clinical application. Considering that some of the proposed cancer applications may require the development of complex systems, this PA would also encourage small business joint ventures to take a modular approach toward development of fully integrated systems for IGI applications in cancer.

SBIR Phase I applications may be submitted in response to this initiative for research on feasibility of systems integration and projection or modeling of performance characteristics of IGI technologies. Phase II applications are expected to focus on one or both tasks of integration and clinical evaluation, depending on the maturity of technologies and complexity of each task. Therefore, technologies that are close to integration are expected to move onto early phase oncologic clinical evaluation during Phase II. This initiative supports the development of multiple prototype IGI systems as required for evaluations in multicenter clinical evaluations.

The scope of the PA also includes the optimization of new imaging protocols, including anatomical, functional, and molecular imaging methods and related spectroscopy techniques required to improve target definition and measurement of the response to interventions, as part of the overall system integration optimization and evaluation. When appropriate, collaborations with NCI funded Centers of Cancer Nanotechnology Excellence (http://nano.cancer.gov/programs/ccne.asp), and cooperative agreement imaging research teams, e.g., Network for Translational Research (U54) and Quantitative Imaging for Evaluation of Responses to Cancer Therapies (U01), (http://imaging.cancer.gov/) are encouraged to allow for more effective translation of IGI systems. Furthermore, such collaborations may help the development of a consensus process on systems validation.

Collaboration(s) with existing NCI-funded center(s) and/or consortium/consortia (e.g., those supported by the NIH P30, U01, U10, U19, U24, and U54 grant or cooperative agreement mechanisms), where the intent is to encourage a broader consensus for the proposed translational research methods or the creation of public research resources for translational research is (are) also encouraged.

When appropriate, small business may find bioinformatics resources in NCI’s cancer BioInformatics Grid (caBIG; https://cabig.nci.nih.gov/), the NCI Image Archive (http://ncia.nci.nih.gov/), or the In-vivo Imaging Workspace (https://cabig.nci.nih.gov/workspaces/Imaging) which provide image data and open source tools of potential utility to validate IGI systems. Furthermore, adaptation of recently established, or under development, DICOM (Digital Imaging and Communications in Medicine; http://medical.nema.org/) standards for Application Hosting (Working Group 23) and Surgery (Working Group 24) will allow for more effective dissemination of IGI technologies in the medical community.

Other Relevant Funding Opportunities

Prospective applicants may also consider the following complementary FOA that supports early phase clinical trials for studying imaging and IGIs in cancer patients or academic-industry partnerships for development and validation of IGI systems:

- Quick-Trials for Imaging and Image-Guided Interventions: Exploratory Grants (R21) (PAR-08-147, http://grants.nih.gov/grants/guide/pa-files/PAR-08-147.html).
- Academic-Industrial Partnerships for Development and Validation of In Vivo Imaging Systems and Methods for Cancer Investigations (R01) (PAR-07-214, http://grants.nih.gov/grants/guide/pa-files/PAR-07-214.html)

For a complete listing of current funding opportunities in imaging, prospective applicants should visit NCI's Cancer Imaging Program website at http://imaging.cancer.gov.